



901 F. 2 Had Street

November 10,1998

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204

## Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Leiner Health Products notifies the FDA that it has begun using the following phrase and statement:

## Maintains a Healthy Emotional Balance

Hypericin, an active ingredient in St. John's Wort, may inhibit the breakdown of specific neurotransmitters and may lead to a feeling of mood elevation.

on the following product:

Tree of Life® St. John's Wort

Very truly yours,

**Leiner Health Products** 

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Manager of Regulatory Affairs

LET 2594